REMARKS

I. STATUS OF THE CLAIMS

Upon entry of this amendment, claims 1-11, 14-29, 31-54, and 67-72 are pending in this application and are presented for examination. Claims 12-13, 30, and 55-66 have been canceled without prejudice to future prosecution. Claims 1-11, 14-29, and 31-54 have been amended. Claims 67-72 are newly added.

Support for the amendments to claims 1 and 32 can be found, *e.g.*, in the instant specification at page 18, lines 28-30; at page 19, lines 15-18; in Figure 8; and in the claims as originally filed. Support for new claims 67 and 68 can be found, *e.g.*, in the instant specification at page 17, lines 14-16. Support for new claim 69 can be found, *e.g.*, in the instant specification at page 17, lines 7-8; at page 19, lines 19-23; and in Figure 7. Support for new claims 70-72 can be found, *e.g.*, in the instant specification at page 14, lines 22 to page 17, line 3; at page 18, lines 28-30; at page 19, lines 15-18; in Figures 7-8; and in the claims as originally filed.

Claims 23, 24, 47, and 50 have been amended to correct typographical errors. Claims 2-11 and 14-29 have been amended to establish proper antecedent basis for the terms recited in claim 1. Similarly, claims 33-54 have been amended to establish proper antecedent basis for the terms recited in claim 32. Claim 14 has also been amended to establish proper dependency from claim 1.

As such, no new matter has been introduced. Reconsideration is respectfully requested.

II. REJECTIONS UNDER 35 U.S.C. §102(a)

Claims 1-8, 12-13, 15-17, 21-22, 32-39, 43-45, 49, 55, 57, and 59 stand rejected under 35 U.S.C. § 102(a) as allegedly being anticipated by Lee *et al.* (U.S. Patent No. 5,908,777) ("Lee *et al.* 1") or by Lee *et al.* (*J. Biol. Chem.*, 271:8481-8487 (1996)) ("Lee *et al.* 2"). Claims 1-6, 8, 12-13, 15-17, 21-22, 28, 32-37, 39, 43-45, 49, 55, 57, and 59 stand rejected under 35 U.S.C. § 102(a) as allegedly being anticipated by Martin *et al.* (U.S. Patent No. 5,891,468). Applicants first note that claims 12-13 and 55-66 have been canceled and are not pending in this

action. To the extent these rejections apply to the presently pending claims as amended, Applicants respectfully traverse these rejections.

For a rejection of claims under § 102 to be properly founded, the Examiner must establish that a single prior art reference expressly or inherently discloses each and every element of the claimed invention. *See, e.g., Hybritech Inc. v. Monoclonal Antibodies, Inc.*, 231 USPQ 81 (Fed. Cir. 1986), *cert. denied*, 480 U.S. 947 (1987); *Verdegaal Bros. v. Union Oil Co. Of California*, 2 USPQ2d 1051, 1053 (Fed. Cir. 1987).

In *Scripps Clinic & Research Found. v. Genentech, Inc.*, 18 USPQ2d 1001 (Fed. Cir. 1991), the Federal Circuit held that:

> Invalidity for anticipation requires that all of the elements and limitations of the claim are found within a single prior art reference... There must be no difference between the claimed invention and the reference disclosure, as viewed by a person of ordinary skill in the field of the invention. *Id.* at 1010.

Anticipation can be found, therefore, only when a cited reference discloses all of the elements, features, or limitations of the presently claimed invention.

Applicants contend that neither Lee *et al.* 1 nor Martin *et al.* nor Lee *et al.* 2 teaches liposomes encapsulating pre-condensed nucleic acid complexes in accordance with the presently claimed invention. Rather, as discussed in Dr. Ian MacLachlan's May 21, 2008 Declaration of record, each of these references teaches a method of rendering DNA less accessible to the Picogreen probe by creating a state in which the exterior portion of an intact pre-formed liposome is wrapped around a DNA/polycation complex (*see*, paragraph 10), and not the state, as presently claimed, wherein the condensing agent-nucleic acid complexes are encapsulated within liposomes.

However, without acquiescing to the merits of these rejections and in an effort to expedite prosecution, Applicants have amended the claims to recite a liposome composition wherein "at least about 30% of the condensing agent-nucleic acid complexes are encapsulated in the liposomes" and "the liposomes are less than about 100 nm in diameter." In view of these

amendments, Applicants submit that the Examiner's rejections are rendered moot. Accordingly, Applicants respectfully request that the present rejections be withdrawn.

III. REJECTIONS UNDER 35 U.S.C. §103(a)

The claims have been rejected in various combinations under 35 U.S.C. § 103(a) over a number of different references. Each of these rejections is discussed in detail below.

A claim is considered obvious "if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains." 35 U.S.C. § 103(a). The Supreme Court in *KSR International Co. v. Teleflex Inc.*, 550 U.S. ___, ___, 82 USPQ2d 1385, 1395-97 (2007) identified a number of rationales to support a conclusion of obviousness which are consistent with the proper "functional approach" to the determination of obviousness as laid down in *Graham*. One of the rationales addressed by the Court in *KSR* supports a finding of obviousness when the prior art reference (or combination of references): (1) teaches or suggests the claim elements; (2) provides some suggestion or motivation to combine the references; and (3) provides a reasonable expectation of success. *See,* MPEP § 2143.

A. Rejection under 35 U.S.C. §103(a) as allegedly obvious over Lee *et al.* 1 (U.S. Patent No. 5,908,777) or Lee *et al.* 2 (J. Biol. Chem.)

Claims 11-14, 26-28, 30-31, 42, 52-53, 56, 58, and 62-63 stand rejected under 35 U.S.C. § 103(a) as allegedly being obvious over Lee *et al.* 1 or Lee *et al.* 2. Applicants first note that claims 12-13, 30, and 55-66 have been canceled. To the extent that the rejections apply to the presently pending claims as amended, Applicants respectfully traverse.

In order to support a rejection under 35 U.S.C. § 103(a), Applicants submit that Lee *et al.* 1 or Lee *et al.* 2 must teach or suggest each of the claim elements. However, neither Lee *et al.* 1 nor Lee *et al.* 2 teaches or suggests all of the elements of independent claim 1, upon which claims 11-14, 26-28, 30-31 depend, or of independent claim 32, upon which claims 42 and 52-53 depend. In particular, neither cited reference teaches or suggests a liposome composition

wherein "at least about 30% of the condensing agent-nucleic acid complexes are encapsulated in the liposomes" and "the liposomes are less than about 100 nm in diameter." Although the Examiner alleges that the cited references teach an encapsulated liposome, the cited references fail to offer any proof of *any* amount of alleged encapsulation, much less "at least about 30%" encapsulation as required by the instant claims. Furthermore, the experiment disclosed in Dr. MacLachlan's May 21, 2008 Declaration of record shows that Lee's method only renders 2.5% of DNA inaccessible (*see,* paragraph 13). Again, this is done by creating a state in which the exterior portion of an intact pre-formed liposome is wrapped around a DNA/polycation complex (*see*, paragraph 10), and not the state, as presently claimed, wherein the condensing agent-nucleic acid complexes are encapsulated within liposomes.

Because Lee *et al.* 1 and Lee *et al.* 2 fail to disclose or suggest all of the elements or limitations of the pending claims, one of the criteria for finding obviousness under the *KSR* rationale is not satisfied, and therefore this rationale cannot be used to support a finding of obviousness. *See,* MPEP § 2143.

Accordingly, Applicants respectfully request reconsideration and withdrawal of this rejection under 35 U.S.C. § 103(a).

B. Rejection under 35 U.S.C. §103(a) as allegedly obvious over Lee *et al.* 1 (U.S. Patent No. 5,908,777), Lee *et al.* 2 (J. Biol. Chem.), or Martin (U.S. Patent No. 5,891,468) further in view of Holland (U.S. Patent No. 5,885,613), Lisziewicz (U.S. Patent No. 6,420,176), and/or Papahadjopoulos *et al.* (WO98/20857)

Claims 8-10, 17-25, 28-29, 39-40, 45-48, 50-51, 53-54, 60, 61, and 63-66 stand rejected under 35 U.S.C. § 103(a) as allegedly being obvious over Lee *et al.* 1, Lee *et al.* 2, or Martin *et al.* in view of Holland *et al.* (U.S. Patent No. 5,885,613), Lisziewicz *et al.* (U.S. Patent No. 6,420,176), and/or Papahadjopoulos *et al.* (WO 98/20857). Applicants first note that claims 12-13, 30, and 55-66 have been canceled. To the extent that the rejections apply to the presently pending claims as amended, Applicants respectfully traverse.

As discussed above, in order to support a rejection under 35 U.S.C. § 103(a), the combination of cited references must teach or suggest each of the claim elements. The instant

claims recite as elements that the liposomes present in the liposome composition encapsulate "at least about 30% of the condensing agent-nucleic acid complexes" and "are less than about 100 nm in diameter." Applicants assert that neither of these elements is disclosed in Lee *et al.* 1, Lee *et al.* 2, or Martin *et al.* Furthermore, the addition of Holland *et al.*, Lisziewicz *et al.*, and/or Papahadjopoulos *et al.* does not cure this deficiency. Because the cited references, taken together, fail to disclose or suggest all of the elements of the pending claims, one of the criteria for finding obviousness under the *KSR* rationale is not satisfied, and therefore this rationale cannot be used to support a finding of obviousness. *See,* MPEP § 2143.

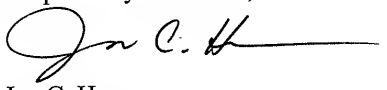
Therefore, Applicants respectfully request the reconsideration and withdrawal of this rejection under 35 U.S.C. § 103(a).

CONCLUSION

In view of the foregoing, Applicants believe all claims now pending in this Application are in condition for allowance and an action to that end is respectfully requested.

If the Examiner believes a telephone conference would expedite prosecution of this application, please telephone the undersigned at 925-472-5000.

Respectfully submitted,



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